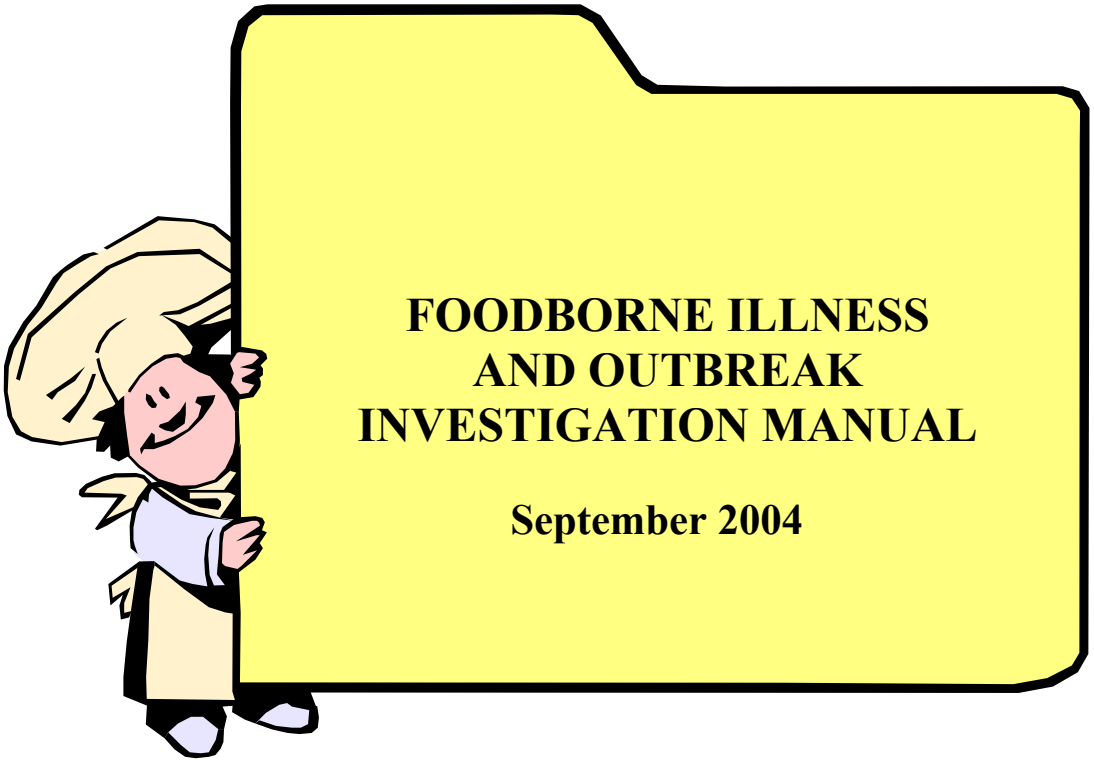

FOODBORNE ILLNESS AND OUTBREAK INVESTIGATION MANUAL

September 2004

Kansas Department of Health and Environment
Division of Health

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PREFACE

The *Foodborne Illness and Outbreak Investigation Manual* (September 2004) is a revised version of the *Foodborne Disease Outbreak Investigations Manual* (November 1997) developed by the Kansas Department of Health and Environment.

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INTRODUCTION

Foodborne pathogens cause an estimated 76 million cases of foodborne illness, 325,000 hospitalizations, and 5,200 deaths in the U. S. annually. Related medical costs and lost wages are significant, accounting for a yearly loss of up to $17 billion[1]. In Kansas, the main bacterial causes of food-related illness are *Salmonella*, *Escherichia coli* O157:H7, *Campylobacter*, and *Shigella*. Viral pathogens, specifically Norovirus (formerly known as Norwalk-like virus) and Hepatitis A virus, are also major causes of foodborne illness in Kansas.

Food-related and other diarrheal illnesses remain underreported throughout the U.S., including in Kansas. Most diarrheal illnesses resolve within 24 to 48 hours without any medical attention. As a result, many food-related illnesses are not diagnosed and associated foodborne disease outbreaks are often not recognized. This poses a challenge for public health professionals to maintain the knowledge and resources to identify and respond to these outbreaks.

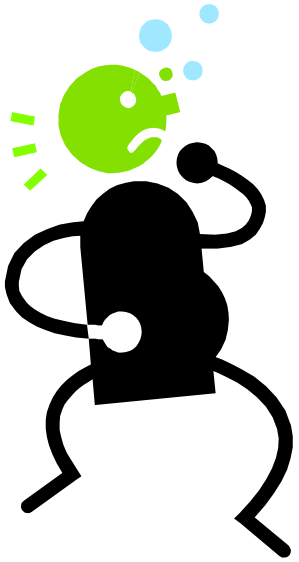
This manual is written primarily for infection control nurses, food inspectors, and outbreak investigators for the purpose of

1. Describing the fundamental concepts related to foodborne illnesses and outbreaks;
2. Discussing the roles and responsibilities of key personnel when responding to foodborne illnesses and outbreaks; and
3. Establishing guidelines for investigating foodborne disease outbreaks in Kansas.

[1] Mead, P.S., et al. "Food-Related Illness and Death in the United States." *Emerging Infectious Diseases*. 1999: 5(5), pp.607-25.

SECTION 1

Foodborne Illnesses



1.1 FUNDAMENTAL CONCEPTS OF FOODBORNE ILLNESSES

Proper and thorough investigation of foodborne disease outbreaks requires a solid understanding of the fundamental concepts related to foodborne illnesses.

> **Foodborne illnesses** refer to diseases acquired through eating or drinking contaminated food or liquids.

Characteristics of Foodborne Pathogens

The most frequent causes of foodborne illnesses include bacteria, bacterial toxins, viruses, and parasites.

Bacteria are one-celled living microorganisms ranging in size from 1 micrometer to 10 micrometers in length. They are naturally found in the environment (often in a spore form) or in various animal reservoirs. Bacteria can multiply in or on food and cause foodborne infections in persons who consume contaminated food or liquids. *Campylobacter* and *Salmonella* are the most reported causes of foodborne infections.

Toxins most often associated with foodborne illnesses are poisons produced or released by certain bacteria. (NOTE: Though certain chemicals and toxins from plants, animals, and fungi can cause illness, this manual will focus mainly on toxin-producing bacteria.) When ingested, bacterial toxins usually act locally within the human body, but may spread to other parts and damage cells, tissues, and the host immune system. *Bacillus cereus*, *Staphylococcus aureus*, and *Clostridium botulinum* are well-documented toxic foodborne agents. *E. coli O157:H7* and *Shigella spp.* also produce toxins that cause disease, which may lead to severe complications. *Staphylococcus aureus* is the most reported cause of foodborne intoxications.

Viruses are minute organisms that reproduce only within living cells. Nonetheless, they can remain infectious in food and may cause foodborne infections in humans. Hepatitis A virus and Norovirus (formerly known as Norwalk-like virus) are the most recognized food-related viruses.

Parasites are single or multi-celled organisms with dimensions greater than 10 micrometers. Like viruses, parasites reproduce within host cells and cannot multiply in food. However, many parasites develop a cyst form that is inert and resistant to the environment. This cyst, when ingested through food or liquids, can multiply within humans and cause foodborne infections. *Giardia lamblia* is the most frequently reported foodborne parasite.

The following table summarizes the characteristics of potential foodborne pathogens.

CHARACTERISTICS OF FOODBORNE PATHOGENS			
	Bacteria	**Viruses**	**Parasites**
Cause infections	✓	✓	✓
Cause intoxications	✓		
Survive in environment	✓	✓	✓
Multiply in environment	✓		
Multiply in host	✓	✓	✓
Multiply in food	✓		
Form spores	✓		
Produce toxins	✓		
Form cysts			✓

Foodborne Transmission of Pathogens and Toxins

Food may become contaminated during food production and processing or during food preparation and handling.

Food production and processing: Animals naturally harbor in their intestines many foodborne bacteria that can cause illness in humans, but often do not cause illness in the animals. During slaughter, meat and poultry carcasses can become contaminated if they are exposed to small amounts of intestinal contents. Other foods, such as fruits and vegetables, may be contaminated if washed or irrigated with water that is contaminated with pathogens from animal or human feces. Thorough cooking of raw foods and washing ready-to-eat foods (i.e. foods not normally cooked or further processed before being eaten) with clean water can decrease the risk of infection.

Food preparation and handling:

- *Cross-contamination*: Pathogens naturally present in one food may be transferred to other foods during food preparation if the same cooking equipment and utensils are used without rinsing in between. If the foods are ready-to-eat foods, contamination can lead to illness.

- *Infected individuals*: Most foodborne pathogens are shed in the feces of infected persons and these pathogens may be transferred to others via the fecal-oral route. In other words, infected individuals, who do not adequately wash their hands after using the toilet, may contaminate the ready-to-eat food that they handle. Even minute quantities of feces, not visible to the naked eye, may contain many pathogens and cause illness. Bacteria present in pus-filled lesions and found naturally in the mucous membrane of the nose may also be transmitted from the hands of an infected foodhandler to ready-to-eat food.

The **fecal-oral route of transmission** describes the ingestion of stool from an infected person or animal through food, water, or direct contact.

- *Inadequate cooking* or *improper holding temperatures*: Under optimal conditions, bacteria may multiply and produce toxins within food. Bacterial toxins that produced are heat stable and may not be destroyed by cooking temperatures.

More information about the environmental factors that influence foodborne illnesses is discussed in Section 2.3.

Classifications of Foodborne Illnesses

Foodborne illnesses are classified as infections or intoxications.

Foodborne infections are caused by consuming foods or liquids contaminated with bacteria, viruses, or parasites. These pathogens cause infection in one of two ways:
- Invading and multiplying in the lining of the intestines and/or other tissues.
- Invading and multiplying in the intestinal tract and releasing a toxin (*Bacteria only*).

Foodborne intoxications are caused by consuming foods or beverages already contaminated with a toxin. Sources of toxins are as follows:
- Certain bacteria. (*Viruses and parasites cannot cause intoxications.*)
- Poisonous chemicals.
- Natural toxins found in animals, plants, and fungi.

Clinical Features of Foodborne Illnesses

The symptoms of most foodborne illnesses include diarrhea, nausea, vomiting, and abdominal cramping. Often mistakenly called the "stomach flu", these symptoms appear on average 24 to 48 hours after infection and last for about 1 to 2 days. Appendix G provides tables that are useful in determining potential causes of foodborne illnesses.

Incubation periods are important clues when determining possible causes of disease. For most diseases, infected individuals can transmit pathogens during the incubation period, when they show no symptoms of illness. For example, an individual, who is infected with the Hepatitis A virus, can shed the virus in his stool (feces) and pass the virus to others two weeks before clinical signs appear or the person feels ill.

Incubation period refers to the interval from the time an individual is infected to the time when symptoms first appear.

The recovery path that follows a foodborne illness can vary according to the pathogen, individual host factors, and antimicrobial use. Antimicrobial use may even shorten or lengthen the recovery period, depending on the pathogen. Similar to the incubation period, individuals may continue to shed the organism in their stool during the recovery period and can potentially infect others.

Recovery period refers to the period when symptoms decline and illness improves.

NOTE: Individuals who harbor an infectious agent but are asymptomatic (i.e. show no symptoms of illness) are considered to be in the **carrier state**. Individuals who are in the incubation period or recovery period of an illness are known as **carriers**.

The following table summarizes the characteristics of infections versus intoxications.

INFECTIONS *vs.* INTO ICATIONS

	Infections	**Intoxications**
Organism	Bacteria Virus Parasite	Toxin
Mechanism	Invade and multiply within the lining of the intestines	No invasion or multiplication
Incubation period	Hours to days	Minutes to hours
Symptoms	Diarrhea Nausea Vomiting Abdominal cramps Fever	Vomiting Nausea Diarrhea Double vision Weakness Respiratory failure Numbness Sensory and motor dysfunction
Transmission	Can be spread person-to-person via the fecal-oral route	Not communicable
Factors related to food contamination	Inadequate cooking Cross-contamination Poor personal hygiene Bare hand contact	Inadequate cooking Improper holding temperatures

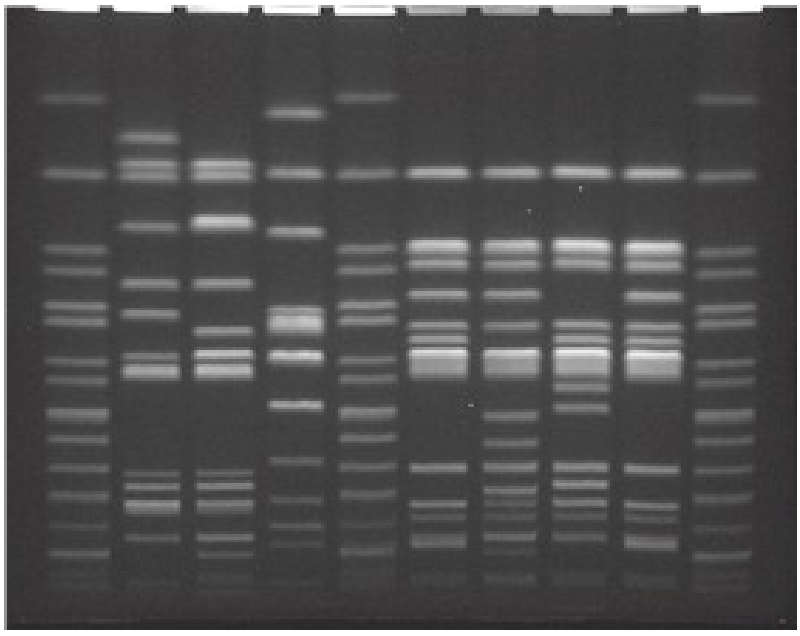
NOTE: The lack of fever in foodborne intoxications may aid investigators when determining the cause of the foodborne illness that is being observed.

Laboratory Diagnosis of Foodborne Illnesses

Most foodborne infections are diagnosed by identification of the pathogen in stool collected from infected persons. Blood samples are recommended for the laboratory diagnosis of systemic infections. The table on the following page provides more information about the laboratory diagnosis of specific diseases.

A laboratory method known as pulsed-field gel electrophoresis or PFGE is a tool used to identify bacterial infections that are food-related. Through this method, the genetic fragments of bacterial isolates are separated by a pulsing electric field. Electric currents move different sized pieces of bacterial DNA through a gel, forming band patterns that look like a barcode. These unique "DNA fingerprints" or band patterns can then be compared and are useful in identifying individuals with matching patterns on a state and national level. Clusters of matching patterns may be indicative of a common source, such as food, and should be further investigated.

The following image is an example of the "fingerprint" pattern of *Salmonella* isolates. Each vertical lane represents a different strain.



Public Health Surveillance and Foodborne Illnesses

Public health surveillance is the routine collection, analysis, summarization, and dissemination of data for the purpose of preventing and controlling the spread of disease.

The Bureau of Epidemiology and Disease Prevention (BEDP) at the Kansas Department of Health and Environment (KDHE) maintains the surveillance system of notifiable diseases for the State of Kansas. This passive surveillance system depends upon the timely and accurate reporting of specific diseases by physicians, hospitals, and laboratories in Kansas to KDHE [Refer to Appendix C for a copy of the Kansas Notifiable Disease Form]. Foodborne illnesses are monitored through this surveillance system to assess disease impact, to detect trends, and to guide interventions.

The following table provides a list of reportable diseases that may be foodborne, their corresponding pathogen, recommended specimens for laboratory diagnosis, and testing capabilities at the KDHE Laboratory (DHEL). Note that some diseases require notification within four hours and some diseases require isolate submission to DHEL.

NOTIFIABLE FOODBORNE ILLNESSES AND CONDITIONS IN KANSAS

Disease or condition	Pathogen	Specimen	DHEL Testing
Bacterial			
Anthrax (gastrointestinal)[1]	*Bacillus anthracis*	Blood	By request only
Botulism (foodborne)[1]	*Clostridium botulinum*	Blood, stool	Refer to CDC
Brucellosis	*Brucella spp.*	Blood	By request only
Campylobacteriosis	*Campylobacter spp.*	Stool	Routinely
Cholera[1]	*Vibrio cholerae*	Stool	By request only
Escherichia coli O157:H7 and other enterohemorhagic, enteropathogenic, and enteroinvasive *E. coli*	*Escherichia coli spp.*[2]	Stool	Routinely
Hemolytic Uremic Syndrome (HUS)	*Usually E. coli*	N/A	N/A
Listeriosis	*Listeria monocytogenes*	Blood, spinal fluid	By request only
Salmonellosis, including typhoid fever	*Salmonella spp.*[2]	Stool	Routinely
Shigellosis	*Shigella spp.*[2]	Stool	Routinely
Viral			
Hepatitis A[3]	Hepatitis A virus	Blood	By request only
Parasitic			
Amebiasis	*Entamoeba histolytica*	Stool	Routinely
Cryptosporidiosis	*Cryptosporidium parvum*	Stool	By request only
Cyclosporiasis	*Cyclospora cayetanensis*	Stool	By request only
Giardiasis	*Giardia lamblia*	Stool	Routinely
Trichinosis	*Trichinella spiralis*	Blood	Refer to CDC

[1] Suspect or confirmed cases should be reported to KDHE within four hours by phone at (877) 427-7317
[2] Isolates must be sent to DHEL for further analysis
[3] Reporting suspect cases to KDHE at (877) 427-7317 is recommended

NOTE: Outbreaks of disease, regardless of the cause, should be reported to KDHE within four hours.

Outbreaks of disease, regardless of the cause, or an unusual occurrence of any disease, including those that appear to be food-related or of public health concern, should be reported to KDHE within four hours. If a diarrheal illness is diagnosed but is not a reportable disease, such as Norovirus, information about this single illness does not need to be forwarded to KDHE.

Epidemiology and Foodborne Illnesses

> **Epidemiology** is defined as "the study of the distribution and determinants of health-related states or events within a specific population, and the application of this study to control health problems."

Last, JM ed. *A Dictionary of Epidemiology*, 3rd ed. New York: Oxford U. Press, 1995:55.

Epidemiologists utilize the elements of surveillance, sound science, and practical common sense to direct action for the purpose of promoting and protecting the public's health. Unlike clinicians who care for the health of the individual, epidemiologists focus on the health of the community. These "disease detectives" collect data to answer the *Who?*, *What?*, *When?*, and *Where?* of disease in the human population and conduct analyses to answer the *Why?* and *How?* to prevent future disease. Infectious disease epidemiologists, in particular, study the frequency and patterns of acute diseases, including foodborne illnesses, to detect outbreaks and implement interventions to prevent further illness.

> An **outbreak** is an unexpected, unexplained increase of disease occurring within a specific population at a given time and place.

1.2 FOODBORNE ILLNESSES, FOOD HANDLERS, AND PUBLIC HEALTH

The Role of Food Handlers

Food handlers are persons who directly handle or prepare food. They may work as paid employees or volunteers, serving food in a variety of settings: food establishments, health care facilities, day cares and schools, community functions, and so on. Therefore, food handlers have an important responsibility to follow safe food preparation and handling practices to prevent illness.

Though food handlers are not at higher risk for developing a foodborne illness compared to other persons, food handlers are at higher *public health* risk for spreading pathogens. Infected food handlers, in particular, represent an extremely high risk for the transmission of pathogens to others through food when bare hand contact with ready-to-eat foods and poor hand washing are present.

The following tables are lists compiled by the Centers for Disease Control and Prevention (CDC) of (1) the pathogens often transmitted by infected food handlers and (2) the pathogens occasionally transmitted by infected food handlers[1]. Also included are the KDHE reporting requirements for the corresponding disease.

Pathogens Often Transmitted by Food Contaminated By Infected Food Handlers

Pathogen	Notifiable Disease in KS
Norovirus	No
Hepatitis A virus	Yes
Salmonella Typhi†	Yes
Shigella spp. †	Yes
Staphylococcus aureus	No
Streptococcus pyogenes	No

† Submission of isolate to the KDHE Laboratory is required.

NOTE: Outbreaks of disease, regardless of the cause, should be reported to KDHE at (877) 427-7317 within four hours.

[1] Centers for Disease Control and Prevention. "Diseases Transmitted Through the Food Supply". Federal Register: November 6, 2003 (Volume 68, Number 215)

Pathogens Occasionally Transmitted by Food Contamination by Infected Food Handlers	
Pathogen	**Notifiable Disease in KS**
Campylobacter jejuni	Yes
Cryptosporidium parvum	Yes
Entamoeba histolytica	Yes
Enterohemorhagic *Escherichia coli*†	Yes
Enterotoxigenic *Escherichia coli*†	Yes
Giardia lamblia	Yes
Non-typhoidal *Salmonella*	Yes
Taenia solium	No
Vibrio cholerae 01	Yes
Yersinia enterocolitica	No

† Submission of isolate to the KDHE Laboratory is required.

NOTE: Outbreaks of disease, regardless of the cause, should be reported to KDHE at (877) 427-7317within four hours.

Because of the potential for food handlers to transmit pathogens through the food they serve, restriction and exclusion requirements have been established for infected food handlers in Kansas. Employees who are excluded cannot work in any capacity in the food establishment until written medical documentation is provided, stating that the person is free of the infectious agent of concern. Employees who are restricted can continue to work in the food establishment, but cannot work with exposed food, clean equipment utensils and linens, or unwrap single-service and single-use articles until restrictions have been removed.

According to the 1999 Kansas Food Code, food handlers who are diagnosed with an illness due to *Salmonella Typhi*, *Shigella spp.*, *Escherichia coli* O157:H7, or hepatitis A virus should be excluded from working in a food establishment. Food handlers suffering from diarrhea, fever, vomiting, jaundice, or sore throat with fever or have a positive stool result for *Salmonella Typhi*, *Shigella spp.*, or *Escherichia coli* O157:H7 should be restricted from food handling, but can serve in another capacity within a food establishment.

More information about exclusion and restriction requirements for certain health conditions is available in Appendix I.

Control Measures for Co-workers of Foodhandlers Infected with Hepatitis A

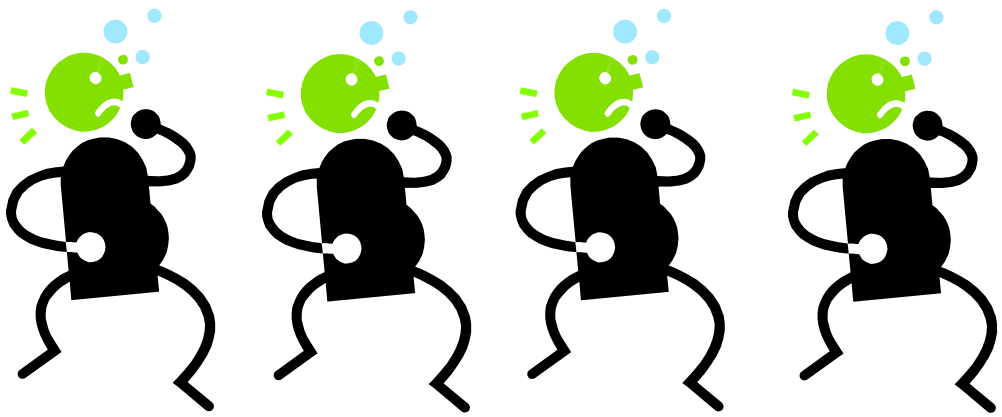
Hepatitis A viral infection among food handlers is of significant public health concern because infected food handlers have the potential to infect many people if they work while infected with hepatitis A, do not practice good hand washing techniques, and have bare hand contact with ready-to-eat food. A food handler who is experiencing symptoms of hepatitis A or has been

diagnosed with hepatitis A must be excluded from food handling until 2 weeks after symptoms first appeared. The excluded food handler should also provide written medical documentation that specifies that the person is free of hepatitis A.

Co-workers, who worked the same days and shifts of an infected food handler, should not be allowed to handle food until they receive a shot of immune globulin (IG) to help prevent hepatitis A or show proof of previous infection or previous vaccination. If the co-workers refuse IG, they are restricted from food handling for 50 days starting from their last contact to the infected food handler during the time when the food handler was still contagious. This is due to the increased likelihood that co-workers will become infected.

SECTION 2

Foodborne Disease Outbreaks



2.1 FUNDAMENTAL CONCEPTS OF FOODBORNE DISEASE OUTBREAKS

Defining a Foodborne Disease Outbreak

In Kansas, a ***foodborne disease outbreak*** is defined in the following ways:

1. **Two or more individuals (from different households) who experience a similar illness after eating a common food[1] or different food from a common place.**
   Household members generally share many meals together and experience close personal contact with one another. Therefore, similar illness among members of a single household is not considered to be a foodborne disease outbreak.

2. **An unexplained, unexpected increase of a similar illness, and food is a likely source.**
   Further investigation to identify the source of infection should be done. For example, an increased number of *Campylobacter jejuni* identified at the state laboratory may suggest that a foodborne disease outbreak has occurred.

NOTE: Positive laboratory identification of the disease-causing organism is not necessary to determine that a foodborne disease outbreak has occurred nor is this identification needed to begin investigation. Many foodborne disease outbreaks have been recognized and successfully investigated even in the absence of any laboratory testing, positive laboratory results, or a definitive diagnosis. Nonetheless, laboratory testing of human specimens and food samples to confirm the pathogen of a foodborne disease outbreak is always encouraged. Refer to Section 2.2 for more information about laboratory testing.

Identifying Foodborne Disease Outbreaks

Foodborne disease outbreaks are identified in several ways, including the following:

- Foodborne illness complaints from private citizens
- Medical evaluations of ill individuals from healthcare professionals at hospitals, clinics, or doctors' offices
- Routine surveillance and case investigation of reportable diarrheal illnesses by epidemiologists and public health nurses at state and local health departments
- Routine laboratory testing and techniques, including pulsed-field gel electrophoresis, conducted by microbiologists
- Information received through the media and public information officers
- Reports from state and federal food safety regulators and environmental health specialists

Reasons for Investigating Foodborne Disease Outbreaks

Once a foodborne disease outbreak has been identified, epidemiologic and environmental outbreak investigations should be implemented for the following reasons:

[1] Food may also include ice, milk, juices, and other liquids that are consumed.

- To identify the cause, the risk factor(s), or source of infection
- To implement interventions, or corrective actions, to prevent others from becoming ill
- To evaluate existing recommendations or strategies for preventing similar outbreaks
- To learn more about the public health implications of foodborne pathogens

Roles and Responsibilities in a Foodborne Disease Outbreak Investigation

Successful foodborne disease outbreak investigations depend upon the coordination of key personnel. Outbreaks are often complex and each function is crucial to the investigation. In most outbreak investigations, the core investigative team is comprised of the local health department infection control nurse, the food inspector, a medical investigator, an epidemiologist, and a microbiologist. During an outbreak investigation, roles and responsibilities may blur, but each component must be completed to successfully investigate an outbreak. The standard roles and responsibilities for each are listed below.

Local Health Department (LHD) Infection Control Nurse

- Oversee all infectious conditions and outbreaks within the county
- Conduct initial investigation of potential outbreaks
- Administer interviews with persons associated with outbreaks
- Distribute stool kits and collect human stool samples for diagnosis
- Submit human specimens and food samples collected for laboratory testing
- Maintain correspondence with local healthcare professionals
- Implement control and prevention measures to stop outbreak from spreading
- Provide educational information about infectious conditions
- Coordinate with food inspector, medical investigator, and epidemiologist

Food Inspector (Local or KDHE)

- Conduct inspection of food establishments
- Identify and address food safety issues that may have contributed to the outbreak
- Interview managers and food handlers about any illness experienced
- Collect food and environmental samples
- Obtain menu of food items served
- Enforce restriction and exclusion state regulations related to food handlers
- Perform Hazard Analysis and Critical Control Points (HACCP) investigation
- Coordinate with LHD infection control nurse and medical investigator or epidemiologist

Medical Investigator (KDHE)

- Serve as the local KDHE contact with LHD infection control nurse
- Assist LHD infection control nurse with disease surveillance and investigation
- Provide technical guidance and overall support to an outbreak investigation
- Facilitate communication between LHDs during inter-county outbreak investigations
- Coordinate with LHD infection control nurse, epidemiologist, and food inspector

Epidemiologist (Local or KDHE)

- Assist in determining if an outbreak has occurred and if an investigation is needed
- Serve as lead investigator or primary coordinator in an outbreak investigation
- Facilitate and guide the steps in an outbreak investigation
- Provide technical, statistical, and overall support to an outbreak investigation
- Maintain communication channels between programs, agencies, counties, and states
- Oversee outbreaks involving multiple counties or states (KDHE)
- Coordinate with LHD infection control nurse, medical investigator, food inspector, and microbiologist

Microbiologist (Local or KDHE)

- Test human specimens or food samples to verify or confirm the diagnosis of the outbreak
- Conduct further subtyping or laboratory analysis, if appropriate
- Coordinate with reference laboratories at other state or federal laboratories
- Coordinate with LHD infection control nurse, medical investigator, or epidemiologist

Other important roles that may or may not be needed for a particular investigation include the following:

Physician / Healthcare Provider

- Report notifiable diseases, including outbreaks, to local or state health department
- Provide clinical information and diagnosis for patients when available
- Assist in the collection of human specimens for laboratory testing

Administrator (LHD)

- Fulfill the role of infection control nurse in many Kansas county health departments
- Assist the LHD staff with outbreak investigations
- May serve as the main liaison with local physicians, the media, or KDHE
- Enforce statutes and regulations related to the health supervision of residents, investigation of causes of disease, and prevention of spread of diseases within the county

Health Officer (LHD)

- Serve as medical consult to county staff
- Enforce statutes and regulations related to the health supervision of residents, investigation of causes of disease, sanitation inspections, and prevention of spread of diseases within the county

Public Information Officer (Local or KDHE)

- Deliver clear, consistent messages related to diseases and outbreaks
- Respond to media requests related to diseases and outbreaks
- Provide educational information to the general public

Federal Personnel

- Provide guidance in national outbreaks or tracebacks
- Assist interstate outbreak investigations

The Importance of Confidentiality

Each of the key players in outbreak investigations has the crucial responsibility of maintaining confidentiality of the individuals involved in the outbreak. Identifying information should **never** be released unless needed to properly conduct the outbreak investigation and protect the public's health. Extreme consideration should be taken to ensure that information is released only on a "need-to-know" basis.

Outbreak Investigations

The purpose of any outbreak investigation is to determine what factors are associated with illness and what measures can be done to prevent further illness. This is achieved through an epidemiologic and environmental investigation. A thorough outbreak investigation cannot be conducted without both components, which are often performed simultaneously.

2.2 CONDUCTING AN EPIDEMIOLOGIC OUTBREAK INVESTIGATION

The main objectives of an epidemiologic outbreak investigation are to identify a problem, to collect information related to the problem, and to develop epidemiologic inferences from which prevention and control measures may be implemented. Facts are collected, usually through a questionnaire, and comparisons of exposures between persons who are ill and who are not ill are analyzed. Conclusions about the outbreak are then formulated from the epidemiologic inferences and the results obtained from the environmental investigation and laboratory testing.

The following table lists the essential steps of an epidemiologic outbreak investigation.

Steps of an Epidemiologic Outbreak Investigation	
1.	Determine that an outbreak has occurred
2.	Contact and coordinate with key personnel
3.	Obtain human and food samples for laboratory testing
4.	Implement control and prevention measures
5.	Organize the information related to the outbreak
6.	Develop possible hypotheses
7.	Plan and conduct the epidemiologic outbreak investigation
8.	Analyze the data collected
9.	Interpret the results and form conclusions
10.	Report investigation methods and findings

The order presented in this manual reflects the logical process of most outbreak investigations conducted in Kansas. However, each outbreak is unique and the investigation should be conducted in a way that ensures that all steps are completed. Several steps may be and sometimes should be conducted simultaneously, emphasizing the importance of a teamwork approach. For instance, control and prevention measures should be implemented as soon as the source of the foodborne outbreak is identified. Nonetheless, the first step in any investigation should be determining if an outbreak has occurred.

NOTE: Good self-study computer-based learning modules can be found at www.phppo.cdc.gov/phtn/casestudies/computerbased.

STEP 1. Determine that an outbreak has occurred

The most important step in any outbreak investigation is to answer the following question:

Has an outbreak occurred

Most reports of foodborne illness are sporadic and are often not associated with a recognized outbreak. The information collected during the initial report may help determine if a foodborne illness complaint is suggestive of an outbreak and whether or not an outbreak investigation is

necessary. This preliminary information may also provide important clues about the cause and source of the outbreak and will help guide the direction of the investigation. Depending upon who receives the initial foodborne illness complaint, an LHD nurse, food inspector, a medical investigator, or epidemiologist is an appropriate person to collect this initial information.

Detailed information that should be collected as soon as possible includes, but is not limited to, the following:

- Date and time food was consumed
- Location where food was prepared and eaten
- Specific food or drink consumed, including ice
- Total number of persons exposed, both ill and not ill
- Number of persons reporting illness
- Date and time of illness onset for each ill person
- Specific symptoms experienced
- Number of doctor visits and hospitalizations
- Number of stool samples collected for testing
    - Recommend testing if not yet done
    - Testing may still be beneficial even if symptoms have ceased
- Specific diagnosis identified, if known
- Other common meals shared
    - Earlier meals may be the more likely source of infection
- Additional information, including specific activities and medications taken before the onset of illness
    - Other factors besides food may have influenced illness
- List of contact information of all persons exposed

The LHD nurse or outbreak investigator may use the "Potential Foodborne Outbreak Worksheet" [Appendix C] to capture much of this information. Food inspectors may use the "Foodborne Illness Complaint Worksheet" [Appendix H], which is provided by the KDHE Bureau of Consumer Health.

As mentioned earlier, a **foodborne disease outbreak** is defined as two or more individuals (from different households) who experience a similar illness after eating a common food or different food from a common place. If only one person reports illness or if only one household is affected, then the report should be handled as a foodborne illness complaint. If the foodborne illness complaint involves a food establishment, an inspection of the establishment should be conducted within 24 hours of the complaint. More information about foodborne complaints may be found in Section 2.3.

If one or more similar reports of illness from different households are received, then an outbreak has occurred and the steps of an outbreak investigation should be conducted.

In some instances, the LHD nurse or outbreak investigator may detect a foodborne outbreak through routine surveillance and observing an unexplained, unexpected increase of a similar illness. This situation suggests the need for further investigation to determine the potential

sources of infection. Completion of the "Seven Day Enteric Questionnaire" [Appendix C] may be useful in collecting pertinent information.

Medical investigators or epidemiologists at KDHE are available at (877) 427-7317 to assist infection control nurses or food inspectors with determining if an outbreak has occurred.

NOTE: When verifying the existence of a foodborne outbreak, other reasons for the increased illness should also be considered, including changes in surveillance criteria, improved reporting, or the introduction of new or revised laboratory detection methods.

STEP 2. Contact and coordinate with key personnel

Once the existence of an outbreak is verified, the next step is to answer the following question:

Who needs to know that an outbreak has occurred

Because of the nature of outbreak investigations, personnel who fulfill key roles in the outbreak investigation process should be notified as soon as possible. A successful investigation requires a teamwork approach and collaboration among, but not limited to, medical investigators, epidemiologists, infection control nurses, food inspectors, microbiologists, healthcare providers, regulators, and the media. Occasionally, foodborne outbreaks may involve individuals in a day care or an adult care setting, and personnel from these entities should also be notified.

The following table lists the agencies that may be involved in an outbreak investigation.

AGENC	PHONE NO.	WHEN TO CONTACT
LOCAL		
Local Health Departments (LHDs)		
Communicable Disease	See directory†	For all outbreaks
Environmental Health	See directory†	If food establishment‡ is involved
Administration	See directory†	If needed
STATE		
Kansas Department of Health and Environment (KDHE)		
Epidemiologic Services	(877) 427-7317	For all outbreaks
Food Protection and Consumer Safety	(785) 296-5600	If food establishment‡ is involved
Diagnostic Microbiology Laboratory	(785) 296-1620	If specimens are submitted
Child Care Licensing and Registration	(785) 296-1270	If day care is involved
Public Information	(785) 296-5795	If needed
Kansas Department on Aging (KDOA)		
Licensure, Certification, & Evaluation Commission	(785) 296-1241	If nursing home, adult care, or long-term care facility is involved

Continued on next page

Kansas Department of Agriculture (KDA)		
Food Safety and Consumer Protection	(785) 296-3511	After 10/1/04* - If retail food store‡ or food processing plant‡ is involved
Laboratory Program	(785) 862-0108	If needed
Public Information	(785) 296-2653	If needed
FEDERAL		
Centers for Disease Control and Prevention (CDC)		
Foodborne Disease and Outbreak Surveillance Unit	(404) 639-1547	If needed
Food and Drug Administration (FDA)		
Kansas City District Office	(913) 752-2100	If a traceback is involved
U.S. Department of Agriculture (USDA)		
Food Safety and Inspection Service (FSIS) District 30	(785) 841-5600	If a traceback is involved

† Directory can be downloaded at www.kdhe.state.ks.us/olrh/download/health_directory.pdf

‡ See Appendix A – Glossary of Terms for definitions.

* Effective October 1, 2004, the Kansas Department of Agriculture will be responsible for conducting food inspections in retail food stores, food processing plants, food service establishments in retail food stores, vending machines and operators, and ice cream trucks.

Most communication will occur between the LHD infection control nurse, the food inspector assigned to the outbreak, the regional medical investigator and an epidemiologist (local or KDHE). Depending upon the county affected and the source of the food (i.e., licensed food establishment, retail food establishment, or food processing plant), food inspectors at contract counties, KDHE, or KDA may need to be contacted.

Medical investigators and epidemiologists at KDHE are available at (877) 427-7317 to assist with coordination and communication of key personnel, especially between state and federal entities.

STEP 3. Obtain human and food samples for laboratory testing

The question to be answered in Step 3 is the following:

What is the organism that caused illness

Human specimens

For most foodborne disease outbreaks, stool samples are collected from persons experiencing diarrhea to identify or confirm the pathogen. Blood cultures or serology testing are recommended for systemic infections, such as *Listeria monocytogenes* or hepatitis A virus. However, serology is less useful for most other foodborne illnesses. Refer to Appendix G for laboratory-confirmation of an outbreak.

Ill persons should be encouraged to submit samples for testing because this information will aid the investigation and the implementation of prevention and control measures.

NOTE:

- **Stool collection should be encouraged whenever a person is experiencing or has recently experienced a diarrheal illness.** If possible, requests for stool samples should begin during the initial foodborne illness report, and such requests may continue throughout the outbreak investigation.
- Testing of all ill individuals is not useful nor is it a good utilization of resources. Collection of five to eight specimens is usually sufficient to confirm the diagnosis.
- Laboratory testing may still be beneficial even after symptoms have ceased. For many foodborne illnesses, an ill person may continue to shed the pathogen in their stool even a few days after symptoms have disappeared and stool appears normal.
- Laboratory testing of individuals who are not ill is not routinely recommended, except when required to remove specific exclusion or restriction guidelines.
- Even in the absence of any laboratory confirmation, positive results, or definitive diagnosis, pathogens may still be implicated and public health measures may be implemented solely based on information collected during the outbreak investigation.

The KDHE laboratory provides two types of stool kits to local health departments: enteric stool kits and ova and parasite (O&P) stool kits. It is recommended that LHDs have three of each kit readily available. The kits have expiration dates, so rotation or replacement is essential. Contact the KDHE laboratory at (785) 296-1620 to order kits and the KDHE Universal Submission Form, which must be completed and submitted with specimens to be tested at the KDHE Laboratory.

Enteric stool kits

- Contain pink to red colored modified Cary-Blair medium (0.16% agar concentration) — the kit should be used only if the medium is this color.
- Most often used for foodborne disease outbreaks.
- Routinely used to test for the presence of the most common bacteria (*Campylobacter, Salmonella, Shigella,* and *E. coli* O157:H7).
- Also used to identify Noroviruses. Testing for Noroviruses is currently conducted at the Public Health Laboratory in Minnesota and requires pre-approval from an epidemiologist at KDHE.
- May be used for toxin testing, though few laboratories in the nation have this capability.

Ova and parasite (O&P) kits

- Contain a vial of formalin and a vial of PVA.
- Routinely used to test for *Giardia lamblia* and *Entamoeba histolytica.*
- Also used to identify *Cryptosporidium parvum* and *Cyclospora cayetanensi,* but a special request to test is required

Food specimens
The pathogen, specifically bacteria or bacterial toxins, may also be identified through food samples. Viral and parasitic identification is extremely difficult. However, food specimens will generally not be tested until the investigation yields a specific food or set of foods suspected and a specific pathogen.

Refer to Appendix D for specific instructions on requesting stool sample kits and submitting stool and food samples to the KDHE laboratory. Appendix D also provides a sample copy of the KDHE Universal Submission Form.

STEP 4. Implement control and prevention measures

Although the source or the cause of the outbreak may remain unknown, the following question should be addressed:

What can be done now to stop illness from spreading

Investigators should respond and implement appropriate public health action as soon as possible. Important control and prevention measures related to foodborne disease outbreaks may include, but should not be limited to, the following:

- Removal of contaminated food
- Exclusion and restriction of persons who are at high risk of spreading illness, including food handlers, day care attendees and providers, and persons involved with patient care
- Emphasizing good handwashing
- Closing the food establishment, if implicated and necessary

As more information becomes available, corresponding measures should also be taken.

After STEP 4, food inspectors should follow the guidelines described in Section 2.3. Nonetheless, it is recommended that food inspectors be familiar with the epidemiologic process.

STEPS 5 – 10 describe steps that LHDs may rely on KDHE medical investigators and epidemiologists for assistance if needed. LHDs may elect to perform these steps themselves if resources permit.

STEP 5. Organize the information related to the outbreak

Important questions to ask at this stage in an outbreak investigation are the following:

What characteristics do the ill persons have in common
What information about the outbreak is available thus far

Outbreaks and their corresponding investigations can quickly become complex. As a result, it is important to try to establish a clear understanding of the outbreak as early as possible. Organizing the preliminary information not only provides clues about the pathogen and its transmission, but also guides the steps of the investigation. Organization and review of existing data is needed before further investigation can effectively begin.

Tools that are used to organize and depict the outbreak include line listings, case definitions, epidemic curves, and maps.

Line listings

A line listing is a table that summarizes information about persons associated with an outbreak. Information often includes identifying information (name, phone number, county of residence), demographic information (date of birth, sex, occupation); date and time of onset and recovery; symptoms experienced (bloody or watery diarrhea, nausea, vomiting, abdominal cramping); and other important factors (specimens submitted, medical visits, hospitalizations, diagnosis, potential exposures).

Example:

						Symptoms				
Name	**DOB**	**Sex**	**Job**	**OnsetD**	**OnsetT**	**D**	**N**	**V**	**AbCr**	**At Recept**
G.H.	08/29/60	F	Vet	07/01/04	1:00a	Y	Y	Y	N	Y
C.T.	11/13/65	F	Nurse	06/30/04	11:00p	Y	Y	N	Y	Y
T.M.	10/11/69	M	Actor	06/30/04	11:45p	Y	N	N	Y	Y
B.O.	01/31/73	M	Teach			N	N	N	N	Y
R.A.	07/27/70	M	Grad			N	N	N	N	Y

KEY:

DOB	Date of birth	N	Nausea
OnsetD	Date of illness onset	V	Vomiting
OnsetT	Time of illness onset	AbCr	Abdominal Cramping
D	Diarrhea (3 or more loose stools in a 24-hour period)	At Recept	Attended wedding reception on Saturday, two days prior to onset

This line listing shows that the three ill individuals experienced similar symptoms around the same time period. In addition, they all attended the same wedding. Based on this information, it is highly likely that these individuals were infected by something served at a wedding reception they attended two days prior to becoming ill.

Case definition

A case definition is a set of criteria for determining who should be classified as a "case", or a person with the particular item(s) of interest. The case definition includes four components: clinical information and information related to time, place, and person.

A case definition may be developed using the line listing information.

Component of definition	uestion asked	Factual item
Clinical criteria	What were the predominant symptoms?	Acute onset of gastroenteritis
Time	When did infection occur?	Saturday evening
Place	Where did infection occur?	Wedding reception
Person	Who may have been affected?	Wedding attendee

In this example, a case could be defined as "any person who experienced any gastrointestinal symptoms after attending the wedding reception on Saturday night". Three persons in the above line listing may be considered cases based on the proposed definition.

As more information becomes available, the case definition can be expanded or refined to ensure that the definition is as specific as needed.

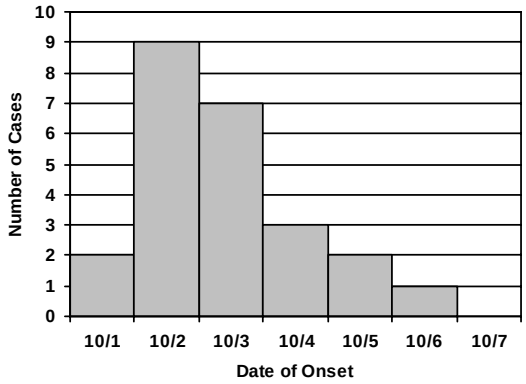
Epidemic Curves

An epidemic curve (epi curve, for short) is a histogram that provides a visual depiction of the outbreak and offers information related to time, the extent of the outbreak, the potential period of exposure, the mode of transmission, and "background noise" or outliers. Outliers can sometimes reveal valuable information about an outbreak, but may also be "red herrings".

Most often, an epi curve plots the incubation period or date of onset of illness on the *x*-axis and the number of ill persons or cases on the *y*-axis. (NOTE: The maximum time period on the *x*-axis should not exceed ¼ to ⅓ of the incubation period, if the incubation period is known.) If the number of cases increases, then new cases are likely to appear in the future and the outbreak is continuing. On the other hand, if the number of cases begins to dwindle, then the outbreak has peaked and is coming to an end. Such information can aid investigators in determining what measures should be taken.

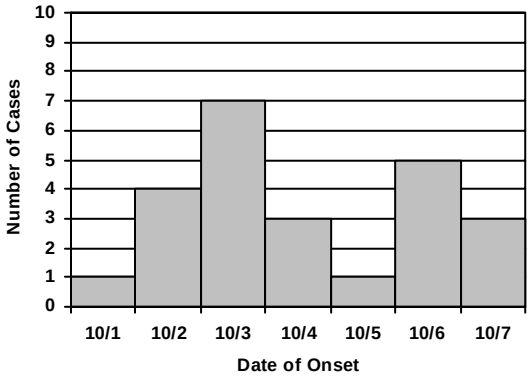
Three main types of outbreaks are depicted through epi curves: common-source or point-source outbreaks, propagated-source or person-to-person outbreaks, and continual-source outbreaks.

Common-source or point-source outbreaks occur when individuals are exposed to some source of infection at the same time. An example of a point-source foodborne disease outbreak is illness experienced by guests who attended and ate food served at the same wedding reception. Foodborne disease outbreaks are most often point-source outbreaks.



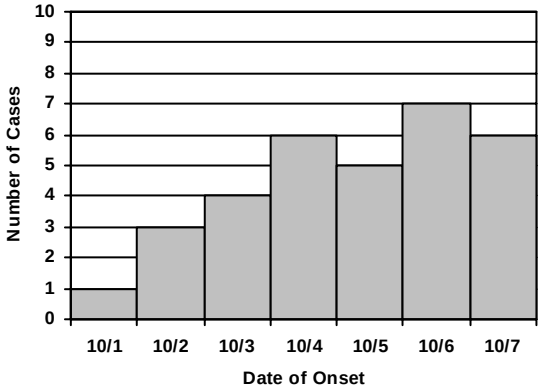
Common-source outbreaks are characterized by a sharp rise in the number of cases that slowly tapers off. Most illness appears within one incubation period.

Propagated-source or person-to-person outbreaks occur when infection is spread from one person to another via the fecal-oral route. An example of a person-to-person outbreak is Noroviral infections within a nursing home. Infection spreads from one resident to another due to poor handwashing and inadequate disinfection.



Propagated outbreaks are characterized by progressive peaks, approximately one incubation period apart.

Continual-source outbreaks occur when a source remains contaminated and illness continues. An example of a continual-source outbreak is a community that continues to use water obtained from a contaminated well.



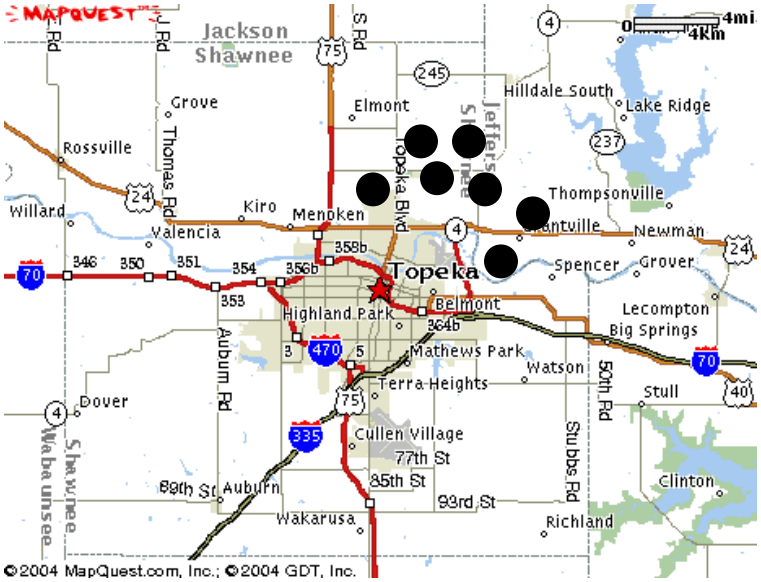
Continual-source outbreaks are characterized by a gradual rise in cases that often plateaus.

Maps and pictures

Maps and pictures are helpful in showing the geographical location or physical layout of the setting in which an outbreak has occurred. This spatial information may be crucial to the outbreak investigation and may provide clues about the source of the outbreak.

The spot map is a well-used pictorial of the spatial distribution of illness within a specific setting or area. In the following example of a spot map, ill individuals are plotted onto a map, with each point representing the residence of an individual. The cluster of cases may indicate a local

exposure in the community. Other spot maps, such as place of employment or school attended, may be useful in some situations.



STEP 6. Develop possible hypotheses

After the preliminary information has been organized, the next question to answer is the following:

What educated guesses can be made

A hypothesis is an educated guess about the cause of the outbreak and the factors that may have contributed to illness. Investigators develop possible hypotheses to guide the direction of the investigation and to initiate appropriate control measures. In most instances, investigators begin to formulate hypotheses during the initial phone call and continue to refine these hypotheses as more information becomes available.

The symptoms experienced, the incubation period, the recovery period, the food items served, the biological plausibility of pathogens, and the tools used to organize the outbreak information provide invaluable clues about the source and cause of illness. The sooner those hypotheses are developed, the sooner that public health interventions may be implemented. Hypotheses may need to be revised during the outbreak investigation, as new information becomes available.

Appendix G provides a table that lists foodborne illnesses and their corresponding incubation periods, signs and symptoms, recovery periods, and foods typically associated with illness. This table may be useful in developing hypotheses related to foodborne disease outbreaks.

STEP 7. Plan and conduct the epidemiologic outbreak investigation

STEP 7 is the focal point of any epidemiologic outbreak investigation. It involves a systematic way of evaluating the hypotheses already developed, of collecting more information about the illness and outbreak, and of answering the following questions:

Why and how did illness occur
What external factors or exposures were associated with illness

The STEPS conducted thus far have focused on the ill persons. However, a thorough outbreak investigation relies upon comparisons of exposures or risk factors among persons who are ill and who are not ill to determine what happened, what may have caused disease, and what can be done to prevent illness in the future.

The questionnaire and the type of study design are important tools used to further analyze an outbreak and make comparisons. Careful planning should be taken when designing the questionnaire, determining the appropriate study design, and organizing the logistics of carrying out the outbreak investigation.

As previously mentioned, LHDs may rely on KDHE medical investigators or epidemiologists at (877) 427-7317 for assistance if needed.

uestionnaire

The questionnaire is a set of questions that captures detailed information from both ill and not-ill persons associated with a foodborne disease outbreak. A questionnaire can revolve around a specific event, a specific menu, or be generalized for foods commonly eaten and establishments frequented. In many instances, the questionnaire may serve as a means of finding more cases and for developing hypotheses. In general, an epidemiologist will be involved in producing an appropriate questionnaire.

The following are the main components of a questionnaire:

- Identifying information
  - Name
  - Address
  - City, County, State, Zip code
  - Phone number (day, evening, and cell)
- Demographics
  - Date of birth or age
  - Sex
  - Occupation
- Clinical information (asked of ill persons only)
  - Specific symptoms experienced
  - Date and time of illness onset
  - Date and time of recovery

    - Medical visits / hospitalizations
    - Specific diagnoses
- Exposure or risk factor information
    - Information related to specific food items consumed
    - Other potential exposures, including specific activities
- Knowledge of illness in others

NOTE: When possible, a menu should be obtained and specific food items, including ice, should be listed in the exposure or risk factor section to help the memory of the persons answering the questionnaire.

Study Design
Two types of studies that utilize the questionnaire to evaluate the association between exposure and illness include cohort and case-control studies.

Cohort studies
A cohort study is appropriate for outbreaks involving a well-defined group of individuals. In these situations, individuals shared a common experience or exposure, and illness may or may not have occurred as a result of the common exposure.

For example: One hundred fifty individuals attended a wedding reception, and many of the attendees consumed food served at this reception. A few days later several attendees reported symptoms of diarrhea, vomiting, and abdominal cramping.

A well-defined group of individuals all shared the common experience of attending the wedding reception and reported illness after consumption of food served at this reception. Based on this information, the cohort study is the best technique for collecting data and analyzing this foodborne disease outbreak.

Ideally, a questionnaire should be administered to all persons (both ill and not-ill) who attended the wedding reception. Comparisons between exposure (in this situation, food served at the reception) and illness may then be made.

Case-control studies
A case-control study is appropriate for outbreaks in which individuals are not part of a well-defined group of individuals. Unlike a cohort study, illness information is known, but exposure information is not. During a case-control study, ill persons ("cases") are matched with not-ill persons ("controls"), and both groups of individuals are asked specific questions to determine if any common exposures exist.

For example: Four cases of *Salmonella typhimurium* were reported during the same time period in the same county. Preliminary case investigation revealed that the unrelated cases consumed food from the same restaurant.

The total number of persons at risk is unknown and not well-defined. Moreover, cases of salmonellosis have been reported, but the association between illness and eating at the restaurant has not been well established. Based on this information, a case-control study is the appropriate method for determining the extent of illness in the community and determining what risk factors may have influenced illness.

Similar to the cohort study, a questionnaire should be administered to both ill ("cases") and not-ill ("controls"). However, an essential component of the case-control study is selecting controls with which the cases may be compared. Ideally, controls should be similar to cases except they do not have the disease and are not ill. Controls should also represent the same population as the cases. In the above example, controls may be found in the community where the restaurant is located.

Controls may be found in the following ways:

- Credit card slips from food establishment, if one is implicated
- Neighbors or individuals from the same community of cases
- Patients from the same physician practice or hospital with a different disease diagnosis
- Friends of cases
- Persons in the phone book who share the same phone prefix

The following table highlights the key similarities and differences between a cohort study and a case-control study used during an outbreak investigation.

COHORT STUD *vs.* CASE-CONTROL STUD in OUTBREAK INVESTIGATIONS

	Cohort Study	**Case-Control Study**
Similarities		
Uses questionnaire to gather data	Yes	Yes
Makes comparisons between ill and not-ill persons	Yes	Yes
Evaluates associations between risk factors and illness	Yes	Yes
Differences		
Population affected	Well-defined	Poorly defined or unknown
Basis for inclusion into study	Common exposure	Presence or absence of illness
Question to be asked	"Did you become ill?"	"Were you exposed?"
Statistical analysis	Attack rates Food-specific attack rates Relative Risk ratios Odds ratios, but less frequently	Odds ratios

When the questionnaire has been developed and the study design has been selected, the logistics of carrying out the investigation should be considered, including the following:

- For a cohort study, a complete list of the group of individuals and their contact information is needed
- For a case-control study, the method for selecting controls needs to be decided
- If possible, the questionnaire should be tested for clarity prior to administration
- The personnel assigned to the study should become familiar with the questionnaire and any potential questions that may arise — LHD nurses and local or KDHE epidemiologists and medical investigators often share the task of conducting interviews
- A feasible method for administering and distributing the questionnaire should be discussed — self-administered or personal interview? In person, by phone, by mail, by electronic mail, or via the Internet?
- The data entry program or spreadsheet and method of entering data into the program should be considered

Once a plan of action has been developed, the outbreak study should be initiated as soon as possible. It may occasionally be necessary for phone calls to be made after hours or on the weekends. The longer the time lapse between exposure and the request for information, the poorer the quality of data that may be collected.

STEP 8. Analyze the data collected

As data is collected, the information may be entered and preliminary analysis may begin even before all interviews are completed to answer the question:

What do the data reveal

The following is a logical method of analyzing the data. Analysis may be performed using any of a variety of analysis software, including EpiInfo, SAS, or SPSS. Appendix E provides more detailed information about the calculations.

Important tasks that should be performed to understand the data include the following:

- Re-evaluate preliminary case definition and ensure that persons classified as cases meet the case definition
- Update any epidemic curves previously plotted
- Conduct frequencies and percentages
- Compute the median and ranges for the incubation period and recovery period
- If the study design was a cohort study, calculate the attack rate, food-specific attack rates, and relative risk ratios
- If the study design was a case-control study, calculate the odds ratios
- Perform tests of statistical significance (i.e., 95% confidence intervals, *p*-values)

STEP 9. Interpret the results and form conclusions

From the initial phone call, detailed information has been collected and organized and hypotheses have been developed. The question to ask at this stage in the investigation is the following:

What can be concluded from all the information collected

Information from the epidemiologic and environmental investigations, the laboratory testing, and general knowledge about foodborne illnesses should be collectively used to help explain what happened, what measures should be taken immediately, and what steps should be taken to prevent similar situations from occurring in the future.

STEP 10. Report investigation methods and findings

Although the outbreak has been contained, documentation is extremely important as a written record of the rationale for the activities in the investigation and to answer the question:

What public health lessons can be learned from this outbreak

Proper reporting of the investigation includes the following:

- Completion of the CDC "Investigation of a Foodborne Outbreak" form [Appendix C] and submission to the Foodborne Disease Coordinator at KDHE [Fax: (877) 427-7418]. This form is used to report foodborne outbreaks in Kansas to the CDC for national surveillance purposes.
- Preparing and writing a report that follows a scientific format of introduction, background, methods, results, discussion, recommendations, and supporting documents. Appendix F provides more information about the final report.
- Dissemination of the final report as widely as needed. At a minimum, the submitter should retain a copy, and additional copies should be provided to the outbreak investigators (local and at KDHE) and any facility involved in the outbreak. Synopses may also be used for press releases and postings on secure websites (e.g., PHIX, Epi-X). Publications in local, regional or statewide documents offer wider review, allowing many others to learn from the experience.

2.3 FUNDAMENTAL CONCEPTS OF FOOD MICROBIOLOG

Familiarity with certain fundamental concepts related to food microbiology is essential to understanding the steps of an environmental outbreak investigation. Such concepts include potentially hazardous foods and the three main hazard categories.

Potentially Hazardous Foods

Potentially Hazardous Foods (PHF) include any food or food ingredient (natural or synthetic) that is capable of supporting rapid growth of microorganisms. Examples of PHFs include beef, poultry, pork, shellfish, dairy products, eggs, raw vegetables, and starchy foods (tofu, rice, potatoes, grains).

Certain conditions favor the growth of foodborne microorganisms within the environmental setting. Such conditions include the food, acidity, time, temperature, oxygen and moisture, collectively known as FAT TOM. (**NOTE**: Viruses and parasites cannot multiply in food or produce toxins.)

The following table describes the concepts of FAT TOM.

Condition	Explanation
Food	Nutrient-rich foods provide a good environment for microorganisms to thrive
Acidity	Bacterial growth is best in neutral or slightly acidic environments — foods with a pH range between 6.6 and 7.5
Time	Two-hour rule — microorganisms proliferate if placed in optimal temperatures for longer than two hours
Temperature	Microorganisms thrive in the "danger zone" (temperatures between 40 deg F and 140 deg F) and some thrive in refrigerated temperatures
Oxygen	The presence or absence of oxygen influences growth of microorganisms
Moisture	Moisture content in foods influences microbial growth — high water activity (>.86) supports rapid growth

The optimum growth temperature range for most pathogens is between 60 deg F and 120 deg F. When bacterial spores are heat shocked into a vegetative state and the contaminated food is held at this temperature range, the bacteria can double in number every 15-20 minutes. Some pathogens, such as *Staphylococcus aureus*, *Bacillus cereus*, *Clostridium botulinum*, and *Clostridium perfringens*, can also produce heat-stable toxins when the contaminated food is

stored at optimum growth temperatures. These toxins, which cannot be destroyed by heating, can remain toxic even after reheating. Other pathogens, particularly *Listeria* and *Yersinia*, proliferate when placed under refrigeration temperature ranges.

NOTE: Most foodborne pathogens survive, but do not grow, at below freezing temperatures and are destroyed at temperatures above 140 deg F.

High-Risk Factors in Food Preparation

Though some foods possess conditions that increase the likelihood of contamination, non-PHFs can still become contaminated and cause foodborne illnesses. As mentioned in Section 1.1, certain risk factors or practices and procedures pose the greatest potential for foodborne illness. The following list provides the three hazard categories and highest risk factors as determined by the CDC and FDA.

Contamination hazard

- Food Source
  - Food from unapproved or uninspected source (e.g., unpasteurized milk)
  - Adulterated food
- Cross-Contamination
  - Raw meats not separated from ready-to-eat foods
  - Equipment not properly cleaned and sanitized
- Poor personal hygiene
  - Lack of appropriate hand washing
  - Bare hand contact with ready-to-eat food
  - Ill food workers
- Environmental contamination
  - Improper storage, labeling, or usage of chemicals
  - Presence of insects or rodents
  - Lack of potable water
  - Improper sewage disposal

Survival hazard

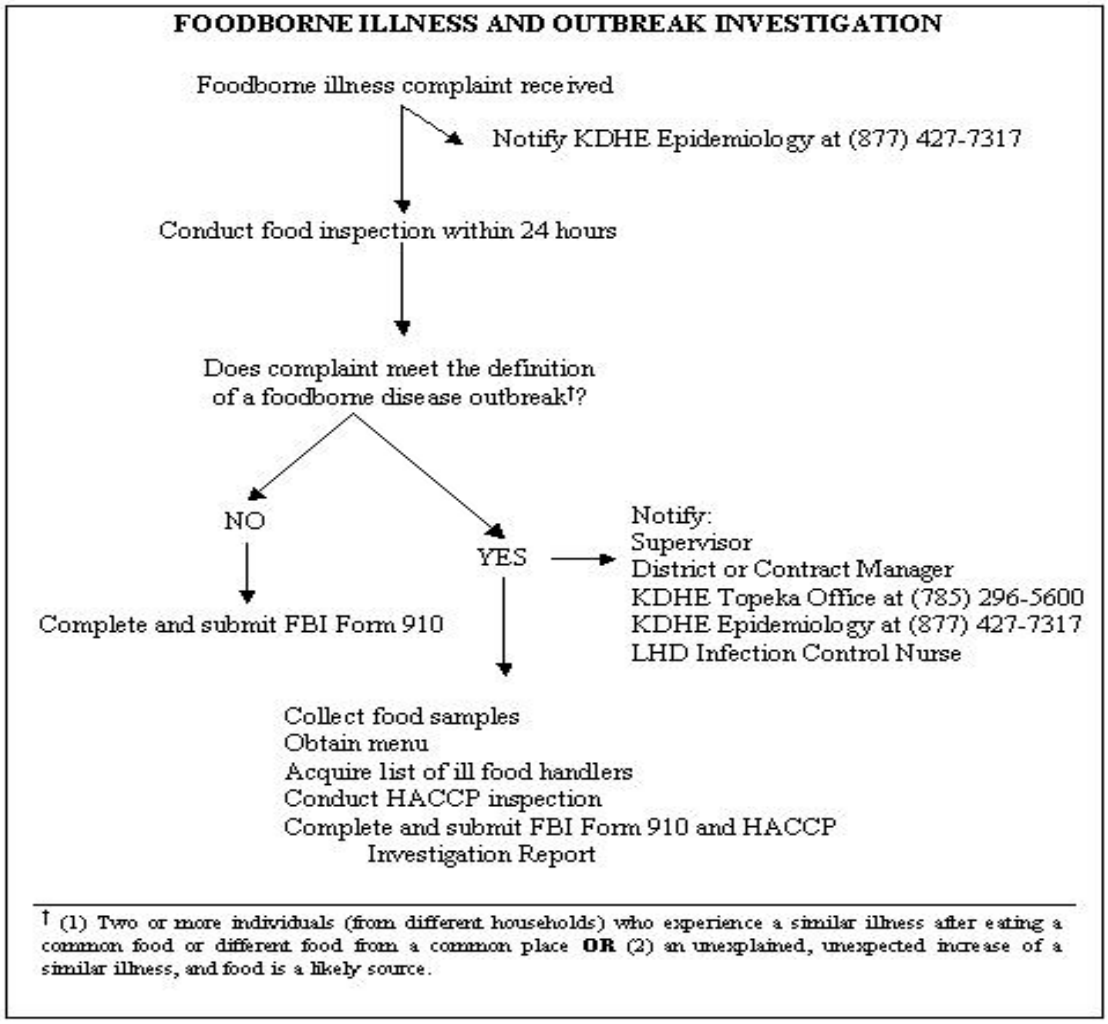
- Inadequate cooking
- Improper reheating temperatures

Growth/Toxin production hazard

- Improper holding
- Unsafe cooling or inadequate refrigeration
- Improper cold/hot holding temperatures
- Preparation several hours before serving

2.4 CONDUCTING AN ENVIRONMENTAL OUTBREAK INVESTIGATION

The main objectives of an environmental outbreak investigation are (1) to identify the contributing factors or source of contamination that may have increased the risk of illness and (2) to implement corrective actions to remove the contamination and enforce safe food preparation and handling practices.



Similar to epidemiologic outbreak investigations, some of the steps may occur simultaneously depending on the situation. Each foodborne illness complaint and outbreak is unique and following the protocol established by KDHE's Food Protection and Consumer Safety Section (FPCSS) may help ensure procedural uniformity.

STEP 1. Inspect food service establishment

Foodborne disease outbreaks may be brought to the attention of KDHE in a variety of ways as mentioned in Section 2.2. Most often, private citizens, who became ill after eating at a food service establishment, report foodborne illness complaints to the LHD or KDHE.

When a foodborne illness complaint is reported, a food inspector should strive to conduct an inspection of the food establishment within 24 hours of receiving the complaint. Often times, complaints are reported days after food is consumed. Nonetheless, timeliness is still important.

Inspectors should make observations and measurements related to high-risk food preparation and handling practices. Corrective actions, including removal of contaminated food, should be conducted accordingly. In addition, food inspectors should interview managers and food handlers about any illnesses experienced and enforce exclusion and restriction requirements as needed.

KDHE Epidemiology at (877) 427-7317 should be notified of all foodborne illness complaints.

NOTE: As previously mentioned, the key players in outbreak investigations have the crucial responsibility of maintaining confidentiality of the individuals involved in the outbreak. Identifying information should **never** be released unless needed to properly conduct the outbreak investigation and protect the public's health. Extreme consideration should be taken to ensure that information is released only on a "need-to-know" basis.

STEP 2. If determined to be a foodborne disease outbreak, contact appropriate personnel and continue with STEPS 3-5

If the foodborne illness complaint meets the definition of a foodborne disease outbreak, several other tasks should be completed, including contacting appropriate personnel, collecting food samples, obtaining a menu, and acquiring a list of ill food handlers.

The inspector should contact and coordinate with the following personnel:

- Supervisor
- District of Contract Manager
- Topeka Office at (785) 296-5600
- KDHE Epidemiology at (877) 427-7317, if not already notified
- LHD infection control nurse, if not already notified

STEP 3. Collect food samples

The food inspector should collect samples of suspect food(s), if still available. [Methods for collecting and submitting samples are found in Appendix D.] Often, the inspection is initiated days after the suspect food was prepared. Sampling of foods may still be helpful, but an epidemiologist should be contacted. The inspector should also obtain a menu to aid the development of the epidemiologic questionnaire and acquire a list of ill food handlers to be further interviewed by the LHD or KDHE outbreak investigator.

STEP 4. Conduct a Hazard Analysis Critical Control Points (HACCP) Inspection

In response to the foodborne illness outbreak notification, the food inspector should conduct a Hazard Analysis Critical Control Points (HACCP) inspection.

> **HACCP** (pronounced HAS-SIP) is a systematic approach to the identification, evaluation, and control of food safety hazards.
>
> *Source*: *FDA Backgrounder*. "HACCP: A State-of-the-Art Approach to Food Safety." http://www.cfsan.fda.gov/~lrd/bghaccp.html

State and local food inspectors are trained to conduct a HACCP inspection, a science-based method of evaluating food handling procedures to identify hazards within the flow of food in an establishment. During a HACCP inspection, the food inspector identifies at critical points the biological, chemical, or physical hazards that may contribute to foodborne illnesses and outbreaks. Specific control measures are subsequently recommended to prevent, eliminate or reduce the hazards.

Appendix J describes in more detail the HACCP principles and the procedures conducted by a food inspector during a HACCP inspection.

STEP 5. Complete and submit Foodborne Illness Form 910 and the HACCP Inspection Report

When the environmental outbreak investigation has been completed, the food inspector should communicate the findings. The Foodborne Illness Form 910 [Appendix H] and the HACCP Inspection Report should be completed, and both should be submitted to the KDHE Topeka Office. This information should also be provided to the corresponding LHD and KDHE outbreak investigators assigned to the outbreak.

Traceback Investigations

Occasionally, an environmental investigation may reveal that a food item associated with foodborne illness may have become contaminated even before arrival to the food service

establishment. In these instances, it is important to trace the implicated food item backwards through the production and distribution chain to identify the contaminated item and remove it from the food market.

Important information that food inspectors should collect when conducting a traceback investigation include the following:

- Label and package information
- Brand name
- Product name
- Package code/lot number
- Expiration/sell by/use by date
- Product size/weight
- Purchase type
- Date of purchase
- Manufacturer name and address
- Distributor name and address (invoice information)
- All retail food establishments where purchased
- Whether or not food is an imported product